MINNESOTA BOARD OF PHARMACY GUIDELINES ADDRESSING THE CANCER DRUG REPOSITORY PROGRAM; MINNESOTA STATUTE 151.55

INTRODUCTION

- The 2005 Minnesota State Legislature passed and Governor Tim Pawlenty signed the cancer drug repository program.
- The Minnesota Board of Pharmacy has been designated by statute to safely establish and maintain a cancer drug repository program.
- Participation in the cancer drug repository program is voluntary.
- Enclosed is a copy of Minnesota Statute 151.55 cancer drug repository program.
- Enclosed are the Minnesota Board of Pharmacy guidelines for the cancer drug repository program.
- Enclosed are the three forms required to comply with the cancer drug repository program statutory language.

MINNESOTA BOARD OF PHARMACY

- The pharmacist responsible for a cancer drug repository program must submit policies and procedures to the Minnesota Board of Pharmacy for review and appropriate actions.
- The submitted policies and procedures must completely address Minnesota Statute 151.55 and the Minnesota Board of Pharmacy guidelines for the cancer drug repository program
- The Minnesota Board of Pharmacy cannot grant a variance to a federal regulation or a Minnesota statute.

GUIDELINES ADDRESSING THE CANCER DRUG REPOSITORY PROGRAM

The cancer drug repository program policies and procedures must address all the provisions of Minnesota Statute 151.55, including use of the three required forms: the participation form, the donation form and the recipient form. (Enclosed)

The cancer drug repository program policies and procedures must address all the following Minnesota Board of Pharmacy guidelines.

1) The policies and procedures must address the participation limit a pharmacy or medical facility chooses and how a partially participating repository will distribute any donated drugs or supplies to a fully participating cancer drug repository. See Minnesota Statute 151.55, subdivision 3.

2) All required forms must be maintained for at least five years.

3) The policies and procedures pertaining to individual eligibility must address how Minnesota Statute 151.55, subdivision 4, requirements will be met, including identification as a Minnesota resident who has been diagnosed with cancer.

4) Policies and procedures must address the donations of cancer drugs and supplies and all the elements of Minnesota Statute 151.55, subdivision 5, including that the donor must be 18 years of age or older and that only if the donated drugs have not been previously dispensed can a pharmacy, medical facility, drug manufacturer, or drug wholesaler donate.

5) A pharmacist, who is employed by or under contract with a cancer drug repository, must determine that the donated drugs or supplies meet all the requirements of the Minnesota Statute 151.55, including that the drug's expiration date must be least six months later than the date the drug was donated; the drug must be in its original manufacturer's unopened, tamper-evident, unit-dose packaging, including lot number and expiration date and the drug must not be adulterated or misbranded. The person making the donation or the person's authorized representative, shall affirm, with a signature on the cancer drug repository donation form, that the donated drugs and supplies were properly stored, never opened, never used and never tampered with, adulterated or misbranded.

6) Controlled substances cannot be part of the cancer drug repository program.

7) Recommend that donated drugs and supplies with special storage or handling requirements only be accepted if donors are able to provide documentation that the special storage or handling requirements have been met.

8) Pharmacists and practitioners need to review the dispensing requirements in Minnesota Statute 151.55, subdivision 6, and address these in the policies and procedures.

9) The cancer drug repository program recipient form [enclosed] must be addressed in the policies and procedures including all elements of Minnesota Statute 151.55, subdivision 6. These include the recipient's right to know that the drugs have been previously dispensed, have not expired, have not been adulterated or misbranded and that the drugs are in their original manufacturer's unopened, tamper-evident, unit-dose packaging. It must be made clear to the recipient that they are making a decision about their treatment, not merely signing a form. (Informed Consent)

10) Policies and procedures for the distribution of donated drugs and supplies to other drug repositories need to be established that address Minnesota Statute 151.55, subdivision 8, including the use of the cancer drug repository program donor form.

11) The policies and procedures must follow the Minnesota Statute 151.55, which states that donated drugs and supplies may not be resold.

12) Drugs used in the cancer drug repository program must be stored separately from the rest of the pharmacy's stock.

13) Recommend a monthly inspection of all cancer drug repository program drugs. This inspection should include checking the expiration date, checking the security of the storage area, and a reconciliation of all the cancer drug repository program drugs and supplies.

14) Cancer drug repository program prescriptions must be filed separately or the pharmacy must have an auditable record system that identifies all necessary information for the cancer drug repository program.

15) All dispensed cancer drug repository program drugs must be verified, have a drug utilization review performed, and be dispensed by a pharmacist or by a practitioner, according to the requirements of Minnesota Statutes Chapter 151 and within the practitioner's scope of practice.

16) All cancer drug repository program drugs must be entered on the patient's profile and the profile must indicate that the drug was obtained through the cancer drug repository program.

17) All drugs dispensed in the cancer drug repository program must be labeled according to Minnesota Rule 6800.3400.

18) All patient-counseling requirements will apply to all drugs dispensed in the cancer drug repository program.

19) There must be a recall procedure for the cancer drug repository program drugs including documentation of all recalls.

20) Recommend a failure mode and effect analysis "FMEA" and a quality improvement "QI" system that addresses the cancer drug repository program, Minnesota Statute 151.55, and the cancer drug repository program policies and procedures.

21) Recommend being fully aware of federal regulations, especially those FDA regulations involving drug adulteration and drug misbranding along with the potential penalties for violations of these regulations.

22) Review Minnesota Statute 151.35 on drug adulteration and Minnesota Statute 151.36 on drug misbranding.

23) Must comply with the Minnesota Hazardous Waste Rule, Chapter 7045, as enforceable by the Minnesota Pollution Control Agency [MPCA] and other authorized state agencies. For information contact the MPCA at 1-800-657-3864 or www.pca.state.mn.us. All these records must be kept for at least five years.

24) All Minnesota Board of Pharmacy statutes and rules must be complied with.

25) Suggest seeking opinions from your legal counsel, risk management, and liability carrier before implementing.

26) All drugs used in the cancer drug repository program should be easily auditable and every dose accounted for. See below for recommended entries for a perpetual inventory logbook.

Suggested information to be contained in a perpetual inventory logbook.

1. Name of drug;
2. Quantity of the drug
3. Expiration date of the drug;
4. Lot number of the drug;
5. Name of person who accepted the drug from the donor;
6. Name of the person who donated the drug;
7. Name of the person to whom the drug was originally prescribed;
8. Name of the person to whom the drug was dispensed;
9. Date the drug was dispensed;
10. Name of the prescribing practitioner who wrote the prescription for the drug to be dispensed under the cancer drug repository program;
11. Name of the medical facility or pharmacy to which the drug was distributed;
12. Date the drug was distributed to another cancer drug repository;
13. Date of destruction or disposal of the drug;
14. Whether a handling fee was charged and the amount of any such fee.